

# METHOD AND APPARATUS FOR CONDITIONING GAS FOR MEDICAL PROCEDURES

This application is a continuation-in-part of U.S. application, Serial No.

- 5 09/081,186, filed May 19, 1998, entitled "Method and Apparatus for Conditioning Gas for Medical Procedures Having Humidity Monitoring and Recharge Alert."

## BACKGROUND OF THE INVENTION

### FIELD OF THE INVENTION

- 10 This invention relates to conditioning gases delivered to body cavities or spaces prior to and during medical procedures. More specifically, it relates to a compact device for, and method of, heating, humidifying and filtering insufflation and other gases.

### 15 RELATED ART

- From the beginning of laparoscopic surgical procedures some thirty years ago, it has been assumed that the condition of gases used to inflate body cavities and spaces were physiologically and pathologically benign. While the importance and use of temperature and moisture conditioning of anesthesia gases has been well known, until  
20 recently little attention had been given to the particulate, temperature and/or humidity condition of insufflation gases used to create a pneumoperitoneum. Reduction in core body temperature, introduction of foreign bodies and drying of surfaces (including peritoneal surfaces), resulting from the introduction of insufflation gases in such surgical procedures are continuing problems.

- 25 A commonly used insufflation gas is carbon dioxide which is typically provided as a liquid in compressed gas cylinders. The pressure in these cylinders, when at equilibrium with ambient environment of 20°C, is 57 atmospheres (5740 kPa). The carbon dioxide gas is typically provided to the surgical site at a pressure of 15 mmHg via an adjustable, throttling pressure regulator and flow controller called an  
30 insufflator. Many models of insufflators are available such as the Storz Model 26012 (Karl Storz Endoscopy-America Inc., Culver City, California). In general, insufflators

do not filter, few have the capability to control the gas temperature, and none are known to have the capability of humidifying the gas.

It is known to filter insufflation gas to prevent inorganic particles such as metallic fillings or particles, rust, dust, and polymer particles from passing into the pneumoperitoneum (*see, e.g., Ott, D.E., J. Gynecol. Surg.*, 5:205-208 (1989)). The location and type of filter, however, are very important factors which will influence the effectiveness of the method. Filters having a pore size as small as 0.2 microns have been used in previous insufflation systems. These devices, however, utilize a filter material that is typically hydrophilic and when it becomes moist, loses its strength and some of its filtering effectiveness. Moreover, because these prior art filter devices are not hydrophobic, they lose their filtering capability by tearing under the water pressure caused by accidentally suctioning or syphoning peritoneal or irrigation fluids.

In addition, in order to compensate for the cool temperature and dryness of the carbon dioxide insufflation gas, an apparatus and method have been developed to control the temperature and humidity of the insufflation gas as it is delivered into the body. Such an apparatus and method are disclosed in commonly assigned U.S. Patent No. 5,411,474 to Ott et al., the entirety of which is herein incorporated by reference. Nevertheless, there is room for improvement of a heating, hydrating and filtering apparatus for the delivery of insufflation gases.

## SUMMARY OF THE INVENTION

The present invention is directed to an apparatus and method for providing humidified, and optionally heated, gas to a patient. The temperature and humidity of the gas may be monitored throughout the procedure.

Briefly, the present invention is directed to an apparatus for conditioning gas for use in a medical procedure, the gas being received into the apparatus from a gas source, such as an insufflator. The apparatus comprises a heater/hydrator having a housing that defines a chamber in which a humidification means and optionally a heating means are disposed in the flow path of the gas through the chamber. The humidification means is a container for liquid disposed in the chamber, and comprises

for example, at least one liquid-retainer layer capable of absorbing a liquid, such as water, for humidifying the gas as it travels through the chamber. The heating means comprises a heating element disposed in the chamber preferably between the liquid-retaining layers. A humidity sensor is provided in the chamber that senses the

5 humidity of the gas in the chamber and a temperature sensor is provided in the chamber to detect the temperature of the gas. A charging port on the housing provides access into the chamber to recharge the chamber with liquid. A monitoring circuit is connected to the humidity sensor that monitors the humidity of the gas exiting the chamber and particularly detects when the chamber requires a recharge of liquid based

10 on the humidity of the gas in the chamber, and generates a recharge signal indicative thereof. An audible and/or visual alarm device may be activated in response to the recharge signal. A control circuit controls electrical power supplied to the heating element to regulate the temperature of the gas exiting the chamber.

Alternatively, or in addition, a backup supply container of liquid is provided

15 that hangs free or is attached to the apparatus. A tube connects the backup supply container to the charging port so that there is an extended supply of liquid to the chamber.

Moreover, the present invention relates to a method of providing, for any selected period of time, conditioned gas into a patient for a medical procedure

20 comprising the steps of directing a gas from a gas source into a chamber; and humidifying the gas within the chamber with a volume of liquid. Optional additional steps are sensing the humidity of the gas as it exits the chamber; and monitoring the humidity of the gas exiting the chamber. The gas from the gas source may be pressure and/or volumetrically controlled. Another optional or additional step is to provide a

25 backup supply for liquid so that there is an extended supply of liquid to the chamber.

The above and other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic view of an apparatus according to the present invention.

Figure 2 is a cross-sectional view of the heater/hydrator of the apparatus according to the present invention.

5 Figure 3 is schematic diagram of a heating element used in the heater/hydrator.

Figure 4 is a cross-sectional view of the heater/hydrator chamber and showing the fluted gas inlet and outlet of the chamber.

Figure 5 is a schematic diagram showing the control circuit for controlling the temperature of the gas and a monitoring circuit for detecting when the humidity of gas  
10 is below a desired humidity level.

Figure 6 is a schematic diagram showing a circuit for monitoring humidity of the gas according to an alternative embodiment.

### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

15 The present invention is directed to a method and apparatus for humidifying or hydrating and optionally heating gas. The humidity of the gas may be monitored and the user informed when the humidity of the gas exiting the apparatus drops below a predetermined or user programmable threshold. The method and apparatus further provides a means to "recharge" the heater/hydrator with liquid, allowing use of the  
20 apparatus for an indefinite period of time. Thus, the apparatus can be used for any endoscopic or other procedure, regardless of its length and regardless of unexpected time delays during the procedure. As an alternative, or in addition, a backup or reserve supply container for liquid is provided to have an extended supply for gas humidification, thereby extending the time period that a medical practitioner can  
25 deliver humidified gas into the patient without having the concern of exhausting the supply and delivering dry gas into the patient.

As used in the claims, "a" can mean one or more.

As used herein, "a predetermined temperature" or "a predetermined temperature range" is one that has been preset or programmed by the user during a procedure. For  
30 example during laparoscopic procedures, the desirable temperature is typically

physiological body temperature, i.e., approximately 35–40°C. As explained hereinafter, the temperature of the gas may be adjusted by a “dial” type or other similar adjustment.

As used herein, the term “liquid” means water (preferably sterile), an aqueous solution, a non-water based solution, or a combination of water or non-water solutions and other substances, such as drugs or anesthetics, or a gel substance containing water or non-water solutions and other substances.

As used herein, any apparatus “immediately adjacent” to a patient or an object indicates a position sufficiently physically close in proximity to the patient or object such that gas at a temperature in the apparatus will not lose more than 2°C while traveling from the apparatus to the interior of the patient or object. Such a distance would be, for example, from about 0-10 inches, preferably from 0 to 10 cm, and more preferably from 0 to 3 cm.

Referring to Figure 1, the apparatus for treating or conditioning insufflation gas is shown generally at reference numeral 100. The apparatus 100 is adapted to receive gas from a gas source (high or low pressure, high or low flow rate), such as insufflation gas from an insufflator 10 for delivery into a body of a patient. The apparatus comprises an optional filter 110, a heater/hydrator 120, and a control module 140. A tubing set is provided to connect the various components of the apparatus together. Specifically, a first tube segment 160 connects the outlet of the insufflator 10 to the inlet tubing of the filter 110 via a male Luer lock 166 or any appropriate adapter compatible with the insufflator outlet port. A second tube segment 162 connects the outlet of the filter 110 to the inlet of the heater/hydrator 120. A third tube segment 164 connects the outlet of the heater/hydrator 120 by a male Luer lock 168 (or other appropriate fitting adapter) to a gas delivery device (not shown), such as a trocar, verres needle, endoscope or a tube that enters a body cavity or space that delivers the filtered, heated and humidified gas into the body of a patient. The tubing of the tube segments 160, 162 and 164 is preferably flexible and sufficiently long to permit the insufflator 10 and control module 140 to be placed at a convenient distance from a

patient undergoing laparoscopic or other surgery or procedure requiring gas distention, while the heater/hydrator 120 is preferably placed immediately adjacent to the patient.

The filter 110 is an optional element and consists of a high efficiency, hydrophobic filter (for example, Gelman Sciences Metrical M5PU025) having a pore size preferably small enough to exclude all solid particles and bacterial or fungal agents that may have been generated in a gas supply cylinder or the insufflator 10 (i.e., 0.5 micron or less and preferably about 0.3 micron). A preferable filter is a hydrophobic filter, such as a glass fiber-type filter, e.g., Metrigard by Gelman Sciences or Porous Media Ultraphobic filter, model DDDF 4700 M02K-GB. Other suitable filters include polysulfone (Supor, HT Tuffrin, Gelman Sciences) and mixed cellulose esters (GN-6 Metrical, Gelman Sciences), for example. Decreasing the pore size of filter 110 below 0.3 micron causes a concomitant increase in pressure drop of gas, and thus flow rate is reduced significantly. If the medical procedure to be performed requires a relatively high pressure and/or flow rate of gas to the patient, such as laparoscopy, the pore size should preferably not decrease below 0.3 micron. A hydrophobic filter is preferable to a hydrophilic one, as a hydrophobic filter is less likely to tear under water pressure caused by accidentally suctioning or syphoning peritoneal or irrigation fluids.

In one embodiment, the heater/hydrator 120 is connected immediately adjacent to a gas delivery device so that the gas travels a minimum distance from the outlet of the heater/hydrator 120 to the conduit or connection to the interior of a patient. The purpose of this arrangement is to allow gas to be delivered to the patient while still at a temperature and water content sufficiently close to the physiological interior body temperature. That is, the apparatus according to the invention prevents thermodynamic cooling of medical gases in transit to the patient, because it provides a highly efficient heating and humidifying chamber that, as a result of its efficiency, can be quite compact and thus be positioned very near to the patient.

The control module 140 is contained within an electrical housing 210 and is connected to the heater/hydrator 120 by several wire pairs contained within an insulated electrical cable 170. In particular, the cable 170 has a connector 172 at one

end that electrically connects into a circuit connector 212 of the housing 210 for the control module 140, and at the other end it is electrically connected to the heater/hydrator 120 by a sealed electrical feedthrough 174. The cable 170 is attached to the tube segment 162 by a plastic tape or clip 176. Alternatively, the cable 170 is  
 5 attached to the tube segment 162 by heat seal, extrusion, ultrasonic welding, glue or is passed through the interior of tube segment 162.

The control module 140 and associated components in the heater/hydrator 120 are preferably powered by an AC-DC converter 180. The AC-DC converter 180 has an output that is connected by a plug connector 182 into a power receptacle 214 of the  
 10 circuit within the control module 140, and has a standard AC wall outlet plug 184 that can be plugged into standard AC power outlets. For example, the AC-DC converter 180 is plugged into an AC power strip that is provided on other equipment in an operating room. Alternatively, electrical power for the apparatus is provided by a battery or photovoltaic source. Another alternative is to provide circuitry in the control  
 15 module 140 that operates on AC signals, as opposed to DC signals, in which case the control module 140 could be powered directly by an AC outlet.

The heater/hydrator 120 has a charging port 190 that is capable of receiving a supply of liquid therethrough to charge the humidification means (described hereinafter) with liquid. For example, a syringe 200 containing a predetermined  
 20 volume of liquid is introduced into the charging port 190 to inject liquid into the heater/hydrator 120 for an initial charge or re-charge of liquid. The apparatus 100 may be sold with the heater/hydrator 120 pre-charged with a supply of liquid such that an initial charge is not required for operation.

Turning to Figure 2, the heater/hydrator 120 will be described in greater detail.  
 25 It is called a "heater/hydrator" though is apparent from this description that, in its basic form, it need only have hydration or humidification elements to humidify a gas stream. The heater/hydrator 120 comprises a housing 122 having an (entry port) gas inlet 124 and an (exit port) gas outlet 126. The housing 122 defines a chamber 128 that contains  
 30 a humidification subchamber for humidifying the gas supplied through the inlet, and in some embodiments, contains elements for substantially simultaneously heating and

hydrating (humidifying), as well as means 136 for sensing the temperature of the gas and means 138 for sensing the relative humidity of the gas as it exits the chamber 128.

Specifically, within the chamber 128, there is provided humidification means which is a subchamber that is preferably comprised of one or more layers of liquid-retaining or absorbing padding or sponge material, shown at reference numerals 130, 131 and 132. It should be understood that the number, spacing and absorbency of the liquid-retaining layers 130, 131 and 132 may be varied according to specific applications. Three liquid-retaining layers are shown as an example. The material of the liquid-retaining layers 130, 131 and 132 can be any desirable liquid-retaining material, such as a rayon/polyester formed fabric (e.g., NU GAUZE™, manufactured and sold by Johnson & Johnson Medical, Inc.). The pore size of the selected material should be chosen according to a balance of liquid-retaining capabilities and low pressure drop considerations. The larger the pore size, the greater the water retention capability for humidification.

Other forms of the humidification means may consist of a subcontainer or subchamber of liquid within the chamber 128 (without liquid-retaining layers) having semi-permeable membrane on opposite ends to allow gas to pass therethrough. The liquid in the chamber could be heated by a heating jacket placed around the chamber to thereby heat and humidify the gas passed therethrough.

The heating means in the heater/hydrator 120 consists of at least one heating element 134 positioned in the housing (substantially) co-located with the humidification means, such as between the liquid-retaining layers 130 and 131. The heating element 134 is an electrically resistive wire, for example, and is described in more detail hereinafter in conjunction with Figure 3. The heating element 134 is positioned within the humidification means insofar as it is placed preferably between liquid-retaining layers. The heating element 134 heats the insufflation gas supplied through the inlet, under control of a heat control signal supplied by the control module 140, substantially simultaneous with the humidification of the gas as the gas passes through the chamber 128. Additional heating elements may be disposed within the chamber.



In order to sense the temperature and humidity of the gas as it exits the heater/hydrator 120, a temperature sensor 136 and a relative humidity sensor 138 are provided. The temperature sensor 136 may be provided anywhere within the flow of gas in the chamber 128, but is preferably positioned on the downstream side of the heating element 134 between liquid-retaining layers. The temperature sensor 136 is a thermistor (for example, Thermometrics MA100 Series chip thermistor, or Thermometrics Series BR23, Thermometrics, Inc., Edison, New Jersey). It is preferable that the temperature sensor 136 be accurate to within about 0.2°C. In the present invention, the temperature of the gas is preferably sensed after the gas has been humidified so that any change in the temperature of the gas as it is humidified is corrected at that point in the apparatus, thereby compensating for enthalpy changes.

The humidity sensor 138 is positioned in the flow path of gas exiting the chamber 128, preferably downstream from the heating element 134 either between liquid-retaining layers or on the downstream side of the liquid-retaining layers, proximate the exit port 126 of the housing 122. The humidity sensor 138 is preferably not in contact with a liquid-retaining layer. Figure 2 shows the humidity sensor 138 distal to the liquid-retaining layers, separated from the liquid-retaining layer 132 by a porous mesh (plastic or metal) layer 133 that extends across the interior of the housing 122. The humidity sensor 138 actually is generally not in contact the porous mesh layer 133, but is spaced therefrom as well. The humidity sensor 138 is a humidity-sensitive capacitor sensor, such as a capacitive humidity sensor manufactured by Philips Corporation, which changes capacitance in response to humidity changes. The humidity sensor 138 measures the relative humidity of the gas as it passes through the chamber 128 to enable monitoring of the gas humidity, and in order to provide an indication of the amount of liquid remaining in the humidification means, i.e., in liquid-retainer layers 130, 131 and 132. As will be explained hereinafter, a timer/divider integrated circuit (IC) 145 (Figure 5), is connected to the humidity sensor 138 and is preferably disposed within the housing 122 together and substantially co-located with the humidity sensor 138.

Electrical connections to the components inside the housing 122 of the heater/hydrator 120 are as follows. A ground or reference lead (not specifically shown) is provided that is connected to each of the temperature sensor 136, heating element 134 and humidity sensor 138-timer/divider 145. A wire 175 (for a positive lead) electrically connects to the heating element 134 and a wire 176 (for a positive lead) electrically connects to the temperature sensor 136. In addition, three wires 177A, 177B and 177C (shown in more detail in Figure 5) electrically connect to the humidity sensor 138-timer divider circuitry, wherein wire 177A carries a DC voltage to the timer/divider 145, wire 177B carries an enable signal to the timer/divider 145, and wire 177C carries an output signal (data) from the timer/divider 145. All of the wires are fed from the insulated cable 170 into the feedthrough 174 and through small holes in the housing 122 into the chamber 128. The feedthrough 174 is sealed at the opening 178 around the cable 170.

The charging port 190 is attached to a lateral extension 139 of the housing 122. The charging port 190 comprises a cylindrical body 192 containing a resealable member 194. The resealable member 194 permits a syringe or similar device to be inserted therethrough, but seals around the exterior of the syringe tip. This allows a volume of liquid (sterile water, etc.) to be delivered into the chamber 128 without releasing the liquid already contained therein. The resealable member 194 is, for example, Baxter InterLink™ injection site 2N3379. Alternatively, the charging port may be embodied by a one-way valve, a sealable port, a screw cap, a cap with a slit to permit the introduction of a syringe or other device, such as a Safeline™ injection site, part number NF9100, manufactured by B. Braun Medical Inc., or any other covering material or member capable of permitting the introduction of a syringe and preventing the backflow of contained liquid or gas. The chamber 128 will contain approximately 3 to 8 cubic centimeters (cc) (but possibly as much as 10 cc) of liquid, and it is desirable that the gas have a dwell time within the chamber of at least approximately 0.01 to 1.0 sec. A liquid volume of 8 cc in the chamber 128 will usually be adequate for conditioning approximately 180 liters of insufflation gas at a desirable relative humidity of 80-95%. The control module 140, however, will issue a warning when the

humidity of the gas being treated by the heater/hydrator 120 drops below a predetermined or user programmable relative humidity, as explained hereinafter.

As an alternative, or in addition to the sensing and monitoring features described above, a backup or reserve supply container for liquid is provided. Referring  
 5 back to Figure 1, one form of a backup supply container is a container 300 that hangs free of the apparatus 100 and is connected with an access tubing 310 to the charging port 190. The container 300 is, for example, a bag such as an intravenous fluid bag and the access tubing 310 is an intravenous type tubing.

Another form of a backup supply container is a container 350 that attaches to a  
 10 portion of the apparatus 100. For example, the container 350 is a reservoir tube, bag, syringe or tank that is attached to the tubing segment 162 or is strapped or fastened to the tubing segment 162 close to the heater/hydrator 120. Another alternative would be to strap or fasten it to the outside of the housing 122 of the heater/hydrator 120. The container 350 is connected to an access tubing 360 that connects into the charging port  
 15 190, similar to access tubing 310 described above.

Access tubing 310 and 360 have a penetrating member (not shown) at their distal ends to penetrate the charging port 190 to gain access to the chamber 128 of the heater/hydrator housing 122. Alternatively, instead of the access tubing 360, the container 350 has at the end proximate the charging port 190 a tip member similar to  
 20 that of the syringe 200 to penetrate and directly couple to the charging port 190.

The containers 300 and 350 can be pre-charged or charged prior to use according to techniques well known in the art. For example, container 350 has an injection site 352 to enable injection of liquid into the container 350.

Preferably, the access tubing 310 or 360 of the backup supply containers 300  
 25 and 350, respectively, (or the integral penetrating tip of the container 350) extend far enough through the charging port 190 so as to make contact with one of the layers 130-132 so that the liquid therein is wicked off onto one of the layers 130-132 due to capillary forces. Alternatively, the access tubing 310 or 360 (or integral penetrating tip of the container 350) stops short of one of the layers 130-132, and the pressure

differential created by the blowing gas stream through the housing 122 will wick off the liquid from the end of these members to contribute to the humidification of the gas.

With reference to Figure 2, another variation is to provide an extension tube 370 that leads from the charging port 190 where the access tubing 310 or 360 (or the integral penetrating tip member of the container 350) terminates, to the humidification subchamber inside the chamber 128, i.e., to contact one or more of the layers 130-132. Liquid is continuously wicked out from the end of the extension tube 370 onto one of the layers 130-132.

In either form of the backup supply container, the basic principle is the same. The backup supply container provides is coupled through the charging port 190 to the humidification subchamber inside the chamber 128 to constantly replenish the humidification subchamber, i.e., one or more of the layers 130, 131 or 132. Consequently, the humidification subchamber will have an initial amount of liquid (pre-charged or charged prior to use) and liquid from the backup supply container is constantly supplied to the humidification subchamber to constantly replenish liquid thereto as gas flows through the chamber. The overall time of sufficient gas humidification is thereby lengthened to a duration that is suitable for all or nearly all medical procedures. As a result, a medical practitioner need not worry or be concerned about decreasing humidity of the gas delivered to the patient. The backup supply container acts a backup to provide gas humidification for an entire procedure. Therefore, some forms of the apparatus 100 need not include the humidity and temperature sensing and monitoring features, or the recharge alert, described herein. These features provide another type of backup that may be useful in certain applications, instead of, or in addition to the backup supply container.

The housing 122 preferably has a length to width ratio of about 1:2 to about 1:10, with a more preferable ratio of about 1:3 to about 1:4. Typically, the length of the housing 122 is from about 0.5 cm to about 1.5 cm, and the diameter can be about 3.0 cm to about 5.0 cm. For example, a preferable housing 122 is approximately 3.5 centimeters (cm) in diameter and 1.0 cm. thick. The length and width of chamber 128 can be varied such that proper heating and humidification occur. An elongated

housing configuration would permit the heater/hydrator 120 to be less intrusive to the medical attendant or surgeon and also be freely movable with respect to other equipment in or around the apparatus 100.

The desirable width and diameter of the chamber is also dependent upon the rate of gas flow from insufflator 10, which is usually from about 1 - 10 liters/minute, and upon the pressure desired to be maintained, which is affected more by the diameter of chamber 128 than by its length. A person of ordinary skill in the art, given the teachings and examples herein, can readily determine suitable dimensions for chamber 128 without undue experimentation. It should also be noted, however, that upon activating the apparatus or changing the demand on the apparatus (e.g., flow rate or pressure), there is a lag time of only several tenths seconds for sensing the temperature of gas and adjusting the heating element to achieve the proper gas or desired temperature. Such a fast start-up time is extremely beneficial.

Referring to Figure 3, the heating element 134 is shown in more detail. The heating element 134 is an electrically resistive wire that is disposed in the housing 128 in a concentric coil configuration having a number of turns, such as 6 - 8 turns. Alternatively, a second heating element 134' is provided that is arranged with respect to the heating element 134 such that its coils are offset from those of the first heating element, relative to the direction of gas flow through the chamber. If two or more heating elements are employed, they are preferably spaced from each other in the chamber of the heater/hydrator by approximately 3 - 4 mm. The first and second heating elements 134 and 134' can be coiled in opposite directions relative to each other. This arrangement allows for maximum contact of the gas flowing through the chamber with a heating element. Other non-coiled configurations of the heating element 134 are also suitable.

Turning to Figure 4, another feature of the heater/hydrator 120 is illustrated. At the inlet and/or outlet of the housing 122, fluted surfaces 123 may be provided to facilitate complete dispersion of gas as it is supplied to the heater/hydrator 120. This improves the fluid dynamics of the gas flow through the chamber 128 to ensure that the gas is uniformly heated and humidified as it flows through the chamber 128.

Referring to Figure 5, the control module 140 will be described in detail. The control module 140 contains monitoring circuitry and control circuitry for the apparatus 100. It is understood that some forms of the apparatus 100 need not include the humidity (and heating) sensing, monitoring and recharge alert functions. The control module 140 comprises a voltage regulator 141, a microcontroller 142, an A/D converter 143, a dual operational amplifier (hereinafter "op-amp") module 144, and a timer/divider 145. The monitoring circuit portion of the control module 140 consists of the combination of the microcontroller 142 and timer/divider 145. The control circuit portion of the control module 140 consists of the microcontroller 142, A/D converter 143 and op-amp module 144. The monitoring circuit monitors the relative humidity of gas exiting the chamber based on a signal generated by the timer/divider 145. The control circuit monitors the temperature of the gas exiting the chamber, and in response, controls electrical power to the heating element to regulate the temperature of the gas to a user programmable or fixed temperature or temperature range. While the temperature of the gas exiting the chamber is actively controlled, the relative humidity of the gas in the chamber is not actively controlled; rather it is monitored and an alert is generated when it drops below a corresponding threshold so that appropriate action can be taken, such as replenishing the heater/hydrator 120 with liquid.

Figure 5 shows that several components are preferably located within the electrical housing 210 (Figure 1), whereas other components are located within the housing of the heater/hydrator 120 (Figure 2). In particular, the timer/divider 145 and the associated resistors R4 and R5 are preferably located inside the housing 122 of the heater/hydrator 120, together with the humidity sensor 138 in a circuit package that includes the humidity sensor 138 exposed on one or more surfaces thereof. More specifically, the timer/divider 145 is co-located with humidity sensor 138. This configuration minimizes timing error by stray wiring inductance and capacitance (sensor kept close to active circuits of timer/divider 145). In addition, by co-locating the timer/divider 145 and humidity sensor 138, the need for interconnecting wires is eliminated, thereby avoiding undesirable signal radiation.

The voltage regulator 141 receives as input the DC output of the AC-DC converter 180 (Figure 1), such as for example, 9 V DC, that is suitable for use by the analog components of the control module. The voltage regulator 141 regulates this voltage to generate a lower voltage, such as 5 V DC, for use by the digital components of the control module. The capacitor C1 at the output of the voltage regulator 141 serves to filter out any AC components, as is well known in the art. Alternatively, a suitable DC voltage is provided by a battery or photovoltaic source shown at reference numeral 149.

The microcontroller 142 may be a PIC16C84 integrated circuit microcontroller that controls system operation. A ceramic resonator 146 (4 MHz) is provided to supply a raw clock signal to pins 15 and 16 of the microcontroller 142, which uses it to generate a clock signal for the signal processing functions explained hereinafter.

The op-amp 144 module is coupled (by wire 176) to the temperature sensor 136 (thermistor) mounted in the housing of the heater/hydrator. The op-amp module 144 is, for example, a LTC1013 dual low-input-offset-voltage operational amplifier integrated circuit that includes two op-amps, referred to hereinafter as op-amp A and op-amp B. The non-inverting input of the op-amp A of the op amp module 144 is pin 3, and pin 2 is the inverting input. The output of op-amp A is pin 1. Op-amp A of the op-amp module 144 is used to buffer the output voltage of the voltage divider formed by resistors R1 and R2. The buffered output voltage, referred to as  $V_x$  in Figure 5, is applied to op-amp B in the op-amp module 144. Op-amp B is configured as a non-inverting-with-offset amplifier with a gain of 21.5, and also receives as input the output of the temperature sensor 136, adjusted by resistor R3, shown as voltage  $V_y$  in the diagram. The output voltage of op-amp B is at pin 7, referred to as  $V_o$  in Figure 5. The output voltage  $V_o$  is equal to  $21.5V_y - 20.5V_x$ , which is inversely proportional to the gas temperature in the housing of the heater/hydrator. The output voltage  $V_o$  ranges between 0 - 5 V DC, depending on the temperature of the gas in the chamber.

The A/D converter 143 is an ADC 0831 integrated circuit analog-to-digital converter that receives as input at pin 2, the output  $V_o$  of the op-amp module 144. The A/D converter 143 generates a multi-bit digital word, consisting of 8 bits for example,

that represents the output voltage  $V_o$ , and is supplied as output at pin 6, which in turn is coupled to I/O pin 8 of the microcontroller 142. The microcontroller 142 commands the A/D converter 143 to output the digital word by issuing a control signal on I/O pin 10 which is coupled to the chip select pin 1 of the A/D converter 143. Moreover, the

5 microcontroller 142 controls the rate at which the A/D converter 143 outputs the digital word by supplying a sequence of pulses on pin 9 applied to clock input pin 7 of the A/D converter 143. The "unbalanced bridge" values of resistors R1, R2 and R3 are chosen to produce a 0 - 5 V DC output over gas temperatures from approximately 20° C to approximately 45° C. Since the bridge and the reference for the A/D converter

10 143 are provided by the same 5 V DC source, error due to any reference voltage shift is eliminated.

The timer/divider 145 is, for example, a MC14541 precision timer/divider integrated circuit. The humidity sensor 138 is connected to pin 2 and to resistors R4 and R5 as shown. In response to an enable signal output by the microcontroller 142 on

15 pin 12 that is coupled to timer/divider pin 6, the timer/divider 145 generates an output signal that oscillates at a rate determined by the value of the resistor R4, the capacitance of the humidity sensor 138 (which varies according to the relative humidity of the gas inside the heater/hydrator housing) and a predetermined divider constant. For example, the divider constant is 256. Specifically, the output signal of

20 the timer/divider 145 is a square wave oscillating between 0 V ("low") and 5V ("high") at a frequency of approximately  $1/[256 \cdot 2.3 \cdot R_4 \cdot C_t]$  Hz, where  $R_4$  is, for example, 56 kOhms, and  $C_t$  is the capacitance at some time (t) of the relative humidity sensor 138 depending on the relative humidity of the gas in the chamber. For example, the humidity sensor manufactured by Phillips Electronics, referred to above, can

25 measure between 10-90%RH (relative humidity), where  $C_t$  at 43%RH is 122 pF (+/- 15%), with a sensitivity of 0.4 +/- 0.5 pF per 1 %RH. The output signal of the timer/divider 145 appears at pin 8, which is coupled to the I/O pin 13 of the microcontroller 142. Thus, the timer/divider 145 is essentially an oscillator circuit connected to the humidity sensor that generates an output signal with a frequency

30 dependent on a capacitance of the humidity sensor. Any oscillator circuit that can



generate as output a signal whose frequency is dependent on a variable capacitance may be suitable for the timer/divider 145.

The microcontroller 142 computes a measure of the relative humidity of the gas inside the heater/hydrator housing by timing or measuring a characteristic of the output signal of the timer/divider 145. Specifically, microcontroller measures the time duration of one of the phases of the output signal of the timer/divider 142, such as the "high" phase which is approximately  $\frac{1}{2} * [256 * 2.3 * R_4 * C]$ . This time duration is indicative of the relative humidity of the gas in the chamber of the heater/hydrator since the rate of the oscillation of the timer/divider depends on the capacitance of the humidity sensor 138, as explained above. For example, for a change in RH of 10-50% and/or 50 to 90%, there is a 13% change in the duration of the "high" phase of the timer/divider output signal. The microcontroller 142 monitors the relative humidity of the gas exiting the chamber in this manner and when it drops below a predetermined or user programmable relative humidity threshold (indicated by a corresponding predetermined change in the oscillation rate of the timer/divider 145), the microcontroller 142 generates a signal on pin 17, called a recharge signal, that drives transistor Q3 to activate an audible alarm device, such as buzzer 147. The buzzer 147 generates an audible sound which indicates that the relative humidity of the gas in the heater/hydrator has dropped below the predetermined or user programmable threshold and that it is necessary to recharge the heater/hydrator with liquid. The relative humidity threshold corresponds to a minimum level for a desirable relative humidity range of the gas exiting the heater/hydrator, and may be 40%, for example. The relative humidity threshold is an adjustable or programmable parameter in the microcontroller 142. Optionally, the microcontroller 142 may generate another warning signal at the output of pin 7 to illuminate an light emitting diode (LED) 148A, thereby providing a visual indication of the humidity dropping below the relative humidity threshold in the heater/hydrator, and the need to recharge the heater/hydrator 120 with liquid. Further, the microcontroller 142 generates a trouble or warning signal output at pin 6 to drive LED 148B (of a different color than LED 148A, for example) when there is either a "code fault" in the microcontroller 142 (an extremely unlikely

occurrence) or when the relative humidity of the gas in the heater/hydrator is less than a critical relative humidity threshold (lower than the relative humidity threshold), such as 10%. In either case, power to the heating element 134 is terminated in response to the warning signal.

5           The microcontroller 142 also controls the heating element 134 in order to regulate the temperature of the gas inside the heater/hydrator. Accordingly, the microcontroller 142 processes the digital word supplied by the A/D converter 143 to determine the temperature of the gas inside the heater/hydrator housing. In response, the microcontroller 142 generates a heat control signal on the output pin 11 that drives  
10 transistor Q1, which in turn drives the MOSFET power transistor Q2, that supplies current to the heating element 134. The temperature of the gas inside the heater/hydrator is regulated by the microcontroller 142 so that it is substantially at a predetermined or user programmable temperature or within a predetermined or user programmable temperature range as it exits the heater/hydrator for delivery into the  
15 body of a patient. For laparoscopy procedures, the temperature range that the gas is regulated to is approximately 35°-40°C, but preferably is 37° C. The control module 140 may include a rheostat or dial-type control to allow a user to adjust the desired temperature or temperature range of the gas that is delivered into the patient. As mentioned above, when the relative humidity inside the heater/hydrator falls below a  
20 critical threshold as determined by the monitoring circuit portion of the control module 140, the control circuit portion in response terminates power to the heating element 134 to prevent the delivery of warm gas that is extremely dry.

          The circuitry for monitoring the relative humidity of the gas can be embodied by other circuitry well known in the art. In addition, while the control module 140 has  
25 been described as having a single microcontroller 142 for monitoring signals representing temperature and relative humidity of the gas exiting the chamber, and for controlling the heating element to control the temperature of the gas, it should be understood that two or more microcontrollers could be used dedicated to the individual functions. In addition, the functions of the microcontroller 142 could be achieved by

other circuits, such as an application specific integrated circuit (ASIC), digital logic circuits, a microprocessor, or a digital signal processor.

Figure 6 illustrates an alternative embodiment for monitoring relative humidity of the gas, in which a humidity sensitive resistor is used, instead of a humidity sensitive capacitor 138. The humidity sensing scheme employing a resistive humidity sensor does not require the timer/divider circuit 145 shown in Figure 5. The humidity sensitive resistor 400 is located inside the heater/hydrator housing in a suitable location for sensing the relative humidity of the gas stream blowing through the heater/hydrator 120. A suitable humidity sensitive resistor is a model UPS600 resistor by Ohmic, which at 45% RH is approximately 30.7 k Ohms. A resistor R10 is coupled in a voltage divider configuration with the humidity sensitive resistor 400. Three pins of the microcontroller 142 couple to the voltage divider formed by resistor R10 and humidity sensitive resistor 400.

Pin 410 of the microcontroller 142 is coupled to one terminal of the resistor R10, pin 412 is coupled to one terminal of the humidity sensitive resistor 400 and pin 414 is coupled to the terminal between the resistor R10 and the humidity sensitive resistor 400. The humidity sensitive resistor 400 may be a type that requires AC excitation. Accordingly, the microcontroller 142 excites the humidity sensitive resistor 400 by applying an alternating pulse, such as a 5 volt pulse, to pins 410 and 12, such that pin 410 is "high" (i.e., at 5 V) for a period of time and pin 412 is "low" (i.e., 0 V), then pin 412 is "high" for a period of time and pin 410 is low. As a result, the average excitation voltage to the humidity sensitive resistor 400 is zero. During the time period when pin 410 is "high", the microcontroller 142 senses the humidity of the gas by determining if the tap voltage pin 414 is a logic "zero" or a logic "one." If it is a logic zero (low voltage), the resistance of the humidity sensitive resistor 400 is low, indicating that the relative humidity of the gas is still high. If it is a logic one (high voltage), then the resistance of the humidity sensitive resistor 400 is high, indicating that the relative humidity of the gas is low. The value of the resistor R10 is chosen to yield a transition at pin 414 at a desired humidity threshold, such as 45% RH, with a 2.5 V transition from a low voltage to a high voltage. For example, resistor R10 is a

30 k Ohm resistor. In the embodiment employing a resistive humidity sensor, a microcontroller that is suitable is a PIC 16C558 in place of the microcontroller model referred to above in conjunction with Figure 5. This sensing scheme can be simplified even further if a relative humidity sensor that allows DC excitation is used. In this case, only one pin of the microcontroller 142 need be associated with humidity sensing.

A resistive humidity sensor has certain advantages over a capacitive humidity sensor. It has been found that the specific type of resistive humidity sensor referred to above can tolerate immersion in water in the heater/hydrator 120 if a user accidentally over-fills the heater/hydrator 120. In addition, the sensing scheme using a resistive sensor does not require a relatively high frequency square wave signal, which may be undesirable in some environments where the apparatus is used. Finally, the resistive sensor affords better accuracy for relative humidity sensing in some applications.

Other variations or enhancements to the circuitry shown in Figure 5 are possible. The type of microcontroller used can be one, such as the PIC16C715, that incorporates the functions of the A/D converter 143. The PIC16C715 microcontroller incorporates a multi-channel A/D converter. In addition, a more feature rich microcontroller of this type will allow for the addition of a display, such as a liquid crystal display (LCD) or LED display. The microcontroller could generate information on a periodic basis to be displayed to the user, such as gas temperature and relative humidity. In addition, the microcontroller may directly drive an audible alert device, rather than indirectly driving it through a transistor as shown in Figure 5. These are examples of the types of modifications or variations that are possible depending on the type of microcontroller that is selected for use in the control module 140.

The volume of gas that can be conditioned with a full supply of liquid in the heater/hydrator depends on the flow rate and pressure used during a procedure. Moreover, the apparatus may be designed to accommodate different anticipated needs for particular procedures. As an example, the chamber of the heater/hydrator is designed to hold 8 to 10 cc of liquid that can humidify 180 liters of gas at a relative humidity level of 80% or more. The microcontroller 142 is programmable to issue the

recharge signal when the humidity of the gas drops below the relativity humidity threshold, independent of the flow rate or pressure of the insufflation gas supply. Preferably, the relativity humidity threshold is set so that brief periods of high pressure or high flow rate do not cause this threshold to be triggered, because the humidity level  
 5 will return to greater-than-threshold levels shortly after the high pressure/flow rate periods ends.

The apparatus 100 may be sold or distributed in a complete set with all of the components shown in Figure 1 (except the insufflator 10), or in modules. One module may be the heater/hydrator 120 and the control module 140 with associated cable 170.  
 10 The optional filter 110 is another module. The tube segments 160, 162 and 164 may be another module. The delivery device 168 may be still another module. For example, the heater/hydrator 120 and control module 140 may be sold by one manufacturer and the tubing set comprising tube segments 160, 162 and 164 may be sold by the same or a different manufacturer. Likewise, the delivery device 168 may  
 15 be sold together with, or separate from, the tubing set.

With reference to Figures 1 and 2, the setup and operation of the apparatus 100 will be described. The AC/DC converter 180 is plugged into a 110V AC power source, such as a wall outlet or a power strip. The control module 140 is connected to the AC/DC converter 180. Alternatively, the apparatus 100 may be powered by a  
 20 battery or photovoltaic source. The heater/hydrating tubing set is then installed by attaching one end of the tube segment 160 to the outlet of the insufflator 10 by the Luer lock 166. The tube segment 160 is attached to the insufflator 10 at one end at to the optional filter 110 at the other end. If the filter 110 is used, then tube segment 162 is connected at one end to it, and at the other end to the heater/hydrator 120. Tube  
 25 segment 164 is then connected to the exit port of the heater/hydrator 120 at one end and to the delivery device 168 at the other end.

The cable 170 is installed into the electrical housing 210 of control module 140 by the connector 172. The heater/hydrator 120 is charged with a supply of liquid by the syringe 200. For example, 8 cc of a liquid, such as sterile water, is drawn into the  
 30 syringe 200. The syringe 200 is then inserted into the charging port 190 so that a

needle or cannula of the syringe 200 penetrates the resealable member 194 (Figure 2) and the liquid is injected into the heater/hydrator 120 to be absorbed by the liquid-retaining layers. The syringe 200 is then removed from the charging port 190, and the charging port 190 seals itself. The free end of the tube segment 164 is attached to a gas delivery device by the Luer lock 168 or other appropriate connector. Alternatively, the heater/hydrator 120 may be pre-charged with liquid, thus not requiring a charge prior to operation. Further, the backup supply container 300 or 350 may be filled with liquid and connected through the charging port 190 to the chamber 128 of the heater/hydrator housing 122.

Once the insufflator 10 is activated, it receives gas from a gas supply cylinder and regulates the pressure and flow rate of the gas, both of which can be adjusted by the operator. The pressure and volumetric flow rate are controlled by adjusting controls (not shown) on the insufflator 10. Insufflator gas then flows through the tube segment 160 into the optional filter 110 where it is filtered, and then through tube segment 162 into the heater/hydrator 120. In the heater/hydrator 120, gas passes through the humidification subchamber, such as the the humidifying liquid-retaining layer(s) 130-132 which are positioned within the flow path of the gas, as shown in Figure 2, passes over the optional heating element 134. In chamber 128, insufflator gas is humidified, or simultaneously heated and humidified if the heating function is provided, to the proper physiological range.

The liquid content of the liquid-retaining layers 130-132 is maintained within a user adjustable or pre-selected range by either the constant replenishment from the backup supply container 300 or 350, or by manually recharging the heater/hydrator 120 by the syringe 200. As a consequence, the relative humidity of the gas exiting the heater/hydrator 120 will be at a desired relative humidity or within a desired range of relative humidity. Optional regulation of the heating element 134 is performed such that the temperature of gas exiting chamber 128 is within a user programmable or fixed physiological temperature range (preferably 35° to 40°C, though any desired temperature range can be preselected). If the apparatus is operated with the heater/hydrator 120 not charged with liquid either because the user forgot to manually

charge it before initiating operation, or the apparatus was sold without a pre-charge of liquid (i.e., in a dry state), the relative humidity of the gas in the chamber of the heater/hydrator 120 will be detected to be below the threshold and the alarm will be activated, alerting the user that the heater/hydrator 120 requires charging of liquid.

- 5 The apparatus will automatically issue an alarm to alert a user to the need for charging the heater/hydrator 120 with liquid, thereby avoiding further delivery of unhydrated gas into a patient.

It should be understood that the more basic forms of the apparatus may involve only humidifying the gas. The components for heating, sensing and monitoring  
 10 humidity and controlling temperature would not be included in a basic form of the apparatus. Similarly, the backup supply container or recharge alert function would not necessarily be included. Other forms of the apparatus may include the backup supply container, with or without the heating, temperature sensing, humidity sensing or recharge alert functions. Similarly, some forms of the apparatus may include the  
 15 heating, temperature sensing, humidity sensing or recharge alert functions with or without the backup supply container feature. The recharge alert function may still be useful in combination with the backup supply container to provide an ultimate warning that even the extended liquid supply has been exhausted, and if the procedure is to continue, the humidification subchamber should be recharged.

- 20 With further reference to Figure 5, the sensing and monitoring operations of the apparatus will be described in greater detail. The control module 140 monitors the relative humidity of the gas exiting the chamber and further regulates the temperature of the gas in the chamber 128. In particular, the microcontroller 142 generates a recharge signal when the relative humidity of the gas in the chamber drops below the  
 25 relative humidity threshold, indicating that the liquid supply in the heater/hydrator 120 requires replenishing. An audible alarm is issued by the buzzer 147 and/or a visual alarm is issued by LED 148A to warn the medical attendant or user that the heater/hydrator 120 requires recharging. Preferably, the microcontroller 142 continues the alarm until the humidity in the chamber returns to a level above the relative  
 30 humidity threshold, which will occur when the heater/hydrator 120 is recharged with

liquid. Moreover, the microcontroller 142 will issue a second alarm, such as by energizing LED 148B, when the relative humidity level of gas in the heater/hydrator 120 drops below the critical relative humidity threshold, at which point electrical power to the heating element 134 is terminated. In addition, the microcontroller 142  
 5 controls the temperature of the gas by controlling electrical power supplied to the heating element 134.

The apparatus and method according to the present invention provide several advantages over similar devices heretofore known, including those disclosed in commonly assigned U.S. Patent No. 5,411,474 to Ott et al.

10 Gas humidification may be maintained within a desirable range by providing a backup supply container for the humidification subchamber or a monitoring and recharge alert function. The monitoring and recharge alert function generate an audible or visual alarm indicating that the heater/hydrator requires recharging of liquid to sustain and provide timed re-supply of liquid in order to maintain a flow of  
 15 heated/hydrated gas. The alarm is maintained until the heater/hydrator is recharged and the humidity of the gas returns to a desirable level (i.e., above the threshold). In addition, the apparatus disclosed herein is easily installed and prepared for use with a minimal amount of lines and tubes. The rechargeable feature of the heater/hydrator eliminates the need for an additional liquid supply tube connected to the  
 20 heater/hydrator, if it is not desirably to have a backup supply container. If needed, the heater/hydrator may be recharged with liquid several times during a procedure.

In addition, the power supply for the apparatus is derived from a standard AC wall outlet or power strip. Power strips are often provided on medical carts already used in the operating room environment. By using a power supply derived from a  
 25 (normally) uninterrupted AC source, as opposed to the finite amount of power that can be supplied by a battery, accommodating surgical procedures that last longer than anticipated is not a concern. The control circuitry for the apparatus is preferably contained in an electrical housing that is relatively movable with respect to the remainder of the apparatus, and therefore can be placed in a non-interfering position in  
 30 the operating room. For example, the electrical housing of the control module can be



attached by tape or Velcro to the side of the insufflator or other stable structure in the operating room, and not encumber the remainder of the apparatus or affect parameter settings of the insufflator.

The method and apparatus of this invention can be utilized for many medical procedures requiring the provision of heated and/or humidified gas. The optional filtration may also be utilized according to the sterility of gas required for the procedure. The gas is chosen according to the procedure to be performed and can be any medically useful gas, such as carbon dioxide, oxygen, nitrous oxide, argon, helium, nitrogen and room air and other inert gases. Preferable gases for endoscopy are carbon dioxide and nitrous oxide. A combination of the above gases can also be used, i.e., 100% of a single gas need not be used. The procedure is preferably endoscopy such as laparoscopy, colonoscopy, gastroscopy, bronchoscopy, and thoracoscopy. However, it may also be utilized for providing heated and humidified oxygen or any anesthetic gases or combination of gases for breathing, for example, or to administer anesthesia or breathing therapy. In particular, the compact size of the apparatus make the invention portable and thus suitable for uses requiring portability. The gas delivery device that provides the direct contact to the patient should be selected according to the medical procedure to be performed as known to those skilled in the art. The gas that is conditioned by the apparatus may be pressure controlled, volumetrically controlled or both.

Throughout this application, various patents publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

Although the present process has been described with reference to specific details of certain embodiments thereof, it is not intended that such details should be regarded as limitations upon the scope of the invention except as and to the extent that they are included in the accompanying claims.